

AT-2plus

Spiro Option

WelchAllyn®
Schiller®

AT-2*plus* Spiro Option User Guide

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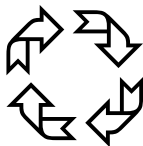
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Terms of Warranty

WELCH ALLYN SCHILLER warrants the AT-2*plus* Electrocardiograph, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of three (3) years from the date of purchase from Welch Allyn or its authorized distributors or agents. Accessory items such as electrodes, batteries and cables are limited to a warranty of 90 days from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchasers responsibility to return the instrument to Welch Allyn or an authorized distributor, agent or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modifications or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commission) Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Disposal Instructions and Battery Care



- DO NOT DISPOSE OF THE BATTERY BY FIRE OR INCINERATOR - DANGER OF EXPLOSION
- DO NOT ATTEMPT TO RECHARGE THE BATTERY - DANGER OF EXPLOSION
- DO NOT OPEN THE BATTERY CASING - DANGER OF ACID BURN

Only dispose of the battery in official recycling centres or municipally approved areas. Alternatively used batteries can be returned to Schiller AG for disposal.

Unit Disposal Instructions

Units no longer required can be returned to Schiller AG for disposal. Alternatively dispose of the unit in municipally approved recycling centres.

Power Supply

The mains connection is on the rear of the unit.

The power supply voltage is set by the factory for 100-115V (nom. 110V) or 220-240V (nom. 230V) working. The setting is indicated by the indented metal strip on the fuse panel. Contact your dealer if the voltage needs to be changed.

The mains indicator lamp on the keyboard is always lit when the unit is connected to the mains supply. The unit can either be operated from the mains supply or from the built-in rechargeable battery. The power source is indicated on the top line of the LCD.

Changing a Mains Fuse

If it is necessary to change a fuse, always replace with the correct rating i.e 2x200mA T for 230V, or 2x315mA T for 110V .

To change a fuse press the two retaining lugs on side of the fuse panel (situated below the mains connector on the back panel. Remove the fuse panel and replace the fuse(s). Click back the fuse panel.

PHYSICIAN'S RESPONSIBILITY

THE AT-2PLUS AND SP-250 SENSOR ARE PROVIDED FOR THE EXCLUSIVE USE OF QUALIFIED PHYSICIANS OR PERSONNEL UNDER THEIR DIRECT SUPERVISION. THE NUMERICAL AND GRAPHICAL RESULTS FROM A RECORDING MUST BE EXAMINED WITH RESPECT TO THE PATIENTS OVERALL CLINICAL CONDITION. THE RECORDING PREPARATION QUALITY AND THE GENERAL RECORDED DATA QUALITY, WHICH COULD EFFECT THE REPORT DATA ACCURACY, MUST ALSO BE TAKEN INTO ACCOUNT.

IT IS THE PHYSICIANS RESPONSIBILITY TO MAKE THE DIAGNOSIS OR TO OBTAIN EXPERT OPINION ON THE RESULTS, AND TO INSTITUTE CORRECT TREATMENT IF INDICATED.

FEDERAL LAW IN THE USA RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Safety Notices

TO PREVENT ELECTRIC SHOCK DO NOT DISASSEMBLE THE UNIT. NO SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.

DO NOT USE THIS UNIT IN AREAS WHERE THERE IS ANY DANGER OF EXPLOSION OR THE PRESENCE OF FLAMMABLE GASES SUCH AS ANAESTHETIC AGENTS.

THIS PRODUCT IS NOT DESIGNED FOR STERILE USE.

THIS PRODUCT IS NOT DESIGNED FOR OUTDOOR USE.

SWITCH THE UNIT OFF BEFORE CLEANING AND DISCONNECT FROM THE MAINS.

DO NOT, UNDER ANY CIRCUMSTANCES, IMMERSE THE UNIT OR CABLE ASSEMBLIES IN LIQUID.

THE DEVICE MUST ONLY BE OPERATED USING BATTERY POWER IF THE EARTH CONNECTION IS SUSPECT OR IF THE MAINS LEAD IS DAMAGED OR SUSPECTED OF BEING DAMAGED.

DO NOT USE HIGH TEMPERATURE STERILISATION PROCESSES (SUCH AS AUTOCLAVING). DO NOT USE E-BEAM OR GAMMA RADIATION STERILISATION.

DO NOT USE SOLVENT CLEANERS

USE ONLY ACCESSORIES AND OTHER PARTS RECOMMENDED OR SUPPLIED BY SCHILLER. USE OF OTHER THAN RECOMMENDED OR SUPPLIED PARTS MAY RESULT IN INJURY INACCURATE INFORMATION AND/ OR DAMAGE TO THE UNIT.

THE AT-2PLUS AND THE SP-250 SENSOR COMPLY WITH EMC REGULATIONS FOR MEDICAL PRODUCTS WHICH AFFORDS PROTECTION AGAINST EMISSIONS AND ELECTRICAL INTERFERENCE. HOWEVER SPECIAL CARE MUST BE EXERCISED WHEN THE UNIT IS USED WITH HIGH FREQUENCY EQUIPMENT.

IT MUST BE ENSURED THAT NEITHER THE PATIENT NOR THE ELECTRODES (INCLUDING THE NEUTRAL ELECTRODE) COME INTO CONTACT WITH OTHER PERSONS OR CONDUCTING OBJECTS (EVEN IF THESE ARE EARTHED).

THIS UNIT IS BF CLASSIFIED ACCORDING TO IEC 601-1.

IF SEVERAL UNITS ARE COUPLED THERE IS A DANGER OF SUMMATION OF LEAKAGE CURRENT

THE DISPOSABLE MOUTHPIECE IS DESIGNED FOR ONE-TIME USE TO ELIMINATE THE DANGER OF CROSS CONTAMINATION - DO NOT USE THE MOUTHPIECE FOR MORE THAN ONE PATIENT.

Intended Use

The AT-2plus with Spiro Option can be used to measure Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV_{1.0}), FEV_{1.0} / FVC, FEF_{0.2-1.2}, FEF_{25-75%}, FEF_{75-85%}, PEF, FEF_{25%}, FEF_{50%}, FEF_{75%}, FIVC, FIV_{1.0}, FIV_{1.0} / FIVC, PIF, FIF_{50%}, SVC, ERV, IRV, TV, MVV, MV, RR, TV, in patients 6 years of age or older.

AT-2plus Spiro Option User`s Guide

This User`s Guide gives instructions on how to operate the Spirometry option of the AT-2plus and provides an overview of all the basic functions in an easy and simple to use format. The procedures are presented in a logical, step-by step way to enable the user to quickly and easily familiarise themselves with unit operation. Detailed medical information is excluded from this guide except where necessary to operate the unit or understand the results.

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CE 0124

93/42/EEC Medical Devices:

0124 `Notified Body` DEKRA AG

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Introduction

The Spirometry function of the SCHILLER AT-2PLUS is automatically available when the SP-250 sensor is plugged into the RS-232 connector on the left hand side of the unit.

It features 4 pulmonary function testing modes for the measurement of inspiratory and expiratory values. The large LCD screen instantly show pulmonary test results along with the normal ECG results and provide a clear and comprehensive result analysis in a number of different formats. All tests and settings are initiated via an easy to use interface with dedicated menu options.

Measurements are made with a lightweight and hygienic open pneumotacho sensor - the SP-250 sensor. This sensor has a disposable, single patient sensor/filter assembly eliminating the need to clean the sensor after each use.

Direct function icons are displayed for measuring the following:

- FVC Forced Vital Capacity
- SVC Slow Vital Capacity
- MVV Maximum Voluntary Ventilation
- MV Expired or Minute Ventilation

CAUTIONS

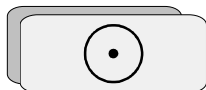
Connect or disconnect the flow sensor only when the unit is turned off. Insert the plug into the socket marked 'RS-232' on the side of the unit. Ensure that the connection cable is not to be exposed to any mechanical stress. Whenever disconnecting the sensor, hold the plug and not the cable.

The flow sensor contains a sensitive measuring device and must always be handled with care. Do not allow the sensor to be dropped or subjected to any sudden blows.

Procedure Overview

WARNING

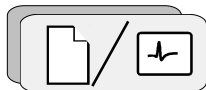
FALSE MEASUREMENTS CAN RESULT WHEN THE SENSOR IS NOT HELD VERTICALLY - ALWAYS ENSURE THAT THE SENSOR IS HELD UPRIGHT AT ALL TIMES.



1. Switch unit on, press ON, the introductory screen is displayed:

2. Press key `ALT` and `P` to enter the Spiro Mode

SP-250
ALT + C = ECG ALT + P = SPIRO



3. Press the Patient key and enter patient data - see page 11.



4. Press the ALT Key to display the menu options.
The pulmonary menu is displayed:

Procedure Overview

Key '1'



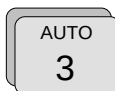
FVC test

Key '2'



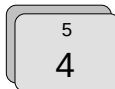
SVC test

Key '3'



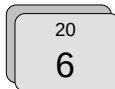
MVV test

Key '4'



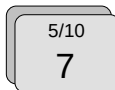
MV test

Key '6'



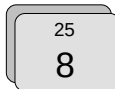
Results

Key '7'



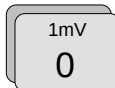
Pre / Post

Key '8'



Calibration

Key '0'



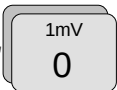
Settings

'M' Memory

'C' ECG

Procedure Overview

5. If using the option for the first time select the required spiro settings and Spiro Standard.

Press '0'  to display the Spiro settings - details of all spiro settings are given on the following pages.

All these settings are stored when the unit is switched off.

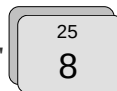
6. Insert new disposable sensor (SP-250).

See page 42

WARNING

THE DISPOSABLE MOUTHPIECE IS DESIGNED FOR ONE-TIME USE TO ELIMINATE THE DANGER OF CROSS CONTAMINATION - DO NOT USE THE MOUTHPIECE FOR MORE THAN ONE PATIENT.

7. Calibrate Unit (print calibration report) - Press key '8'



The unit must be calibrated

- **At the beginning of each day**
- **If the sensor is changed**
- **When a significant temperature or pressure difference occurs**

The calibration procedure is detailed on page 21.

Procedure Overview

8. Select test:

Forced Vital Capacity (FVC) Test



For this test the patient must exhale as quickly as possible from the time of starting the test.

Note: **The FVC test employs the `Back extrapolation` method. If the extrapolated volume is too large (>0.15 litres or 5% of FVC), then a warning appears on the display**

To carry out the test for Forced Vital Capacity (FVC), press key `1` and the corresponding coordinate presentation appears on the display.

The patient must exhale as quickly as possible from the time of starting the test so be sure that he understands what is required of him. If inspiratory measurements are required, the exhalation can be immediately followed by a maximum inhalation. The inspiration results will be given on the printout.

The coordinates represent the graph on which the curve will be drawn with the respiratory volume in litres being represented on the vertical axis and the time in seconds on the horizontal axis.

ALSO SEE `SPIROMETRY TIPS` AT THE END OF THIS BOOK

Procedure Overview

Slow Vital Capacity (SVC) Test



The patient should breathe normally 3 times and then inhale maximally to total lung capacity and then expire maximally. Make sure that the patient understands what is required of him.

MVV Test



The patient should breathe as deeply and as rapidly as possible over a period of 6 to 12 seconds.

WARNING EXTREME CARE SHOULD BE EXERCISED WHEN PERFORMING THIS TEST AS THERE IS A DANGER OF HYPERVENTILATION. ENSURE THAT THE PATIENT IS SITTING DOWN.

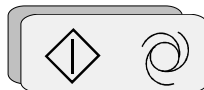
MV Test



The patient should breathe as normally as possible for up to 60 seconds, but for at least 20 seconds.

Procedure Overview

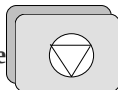
9. Click the Auto (START) key



The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

The message “READY FOR MEASUREMENT” appears on the display together with a volume counter graph for the value. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the expiratory flow. The corresponding curve is represented on the display. The break-off point for the expiration measurement is reached automatically (or the Stop key is pressed).

10. Press the STOP key on completion of the test.



Screen Information

Once the test is completed, the measurement results are calculated and given on the display. When subsequent tests are made, the result with the highest $FVC + FEV_1$ value will always be saved and given in the column MEAS 1.

The result with the lowest $FVC + FEV_1$ value of the tests already made and stored will be overwritten.

NOTE: The marked results correspond to the displayed test curve.

Procedure Overview

11. Repeat as many times as required (Best, or Meas. 1).

Repeat steps 8 and 9 until three measurements have been taken.

Note: If the Start key is again pressed (a fourth or more times), only the best three measurements are stored.

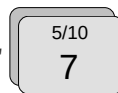
When American standards are stipulated, the message ,`ATS criteria met` appears on the printout if the deviation (as stipulated by the American Thoracic Society) between the best and second best measurements is not greater than 200ml.

Following a series of patient measurements the best two results are recorded and stored along with the last test made (which may or may not be one of the best three). These three results can then be printed graphical along with a table of the best individual measurements (from these three results). The table of the best measurements can also be displayed on the screen.

12. **Dispose of the mouthpiece immediately after completing the tests (page 42) to eliminate the danger of cross infection.**

Post-Medication Tests

In order to carry out post-medication tests for comparison, press key '7'



The post-medication tests are carried out in the same way as the premedication tests (three measurements stored). The printout following post-medication tests will give the curves of both pre and post-medication tests (the premedication curve is bold). The measurement results are shown as the best results (pre/post), results as a percentage of those predicted, (both pre and post) and the percentage change (i.e. difference) between pre and post-medication results.

The diagnosis resulting from the premedication test is also given on this printout.

Definition of Best

In accordance with the ATS Spirometry Standard (11 November 1994), the best recordings are defined as the highest value from the calculation:

$$\text{Best} = \text{FVC} + \text{FEV1}$$

The measurement table (on the printout and on the display) gives the highest individual measurements (e.g. FVC, FEV1, SVC, MVV etc.) from the best three recordings as defined above. This is true for all parameters except the following which are based solely on the highest FVC + FEV1 value:

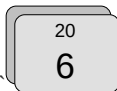
- $\text{FEF}_{0.2 - 1.2}$
- $\text{FEF}_{25\% - 75\%}$
- $\text{FEF}_{75\% - 85\%}$
- $\text{FEF}_{25\%}$
- $\text{FEF}_{50\%}$
- $\text{FEF}_{75\%}$
- $\text{FIF}_{50\%}$

Entering Patient Data

Each printout is complete with the name and other information concerning the patient. Before beginning a recording, the patient data should be entered. The following parameters have to be entered:

Pat-Name:	Patient name
Pat-No:	Patient number
Age:	Enter age of patient in whole years
Sex:	Select `M` (male) or `F` (female).
Height:	Height in centimetres (or inches (scaled to 1/10 inch), if American language set).
Weight:	Weight in kilogrammes (or pounds, depending on unit setup).
Ethnic:	Enter patients race: W/B: `W` for White, `B` for Black (all languages except American - see page 20) C/H/B/A: `C` for Caucasian, `H` for Hispanic, `B` for Black or `A` for Asian (American only - see page 20)

Displaying the Results in Tabular Form



Press the Results option key `6` after a measurement, or series of measurements have been made. A measurement table is displayed.

The display gives the measured values and the predicted values* (calculated from the entered patient data). **The predicted values can only be calculated when the patient data has been entered.**

The result displayed is in accordance with ATS recommendations and is the best result *for each individual parameter*, from the three tests recorded.

When subsequent tests are made, the result with the highest value will always be saved and given in the measurement column.



Press the  key to return to the graphic display. An example of the FVC measurement screen is shown opposite. The measurement table for all parameters are similar.

* *The predicted values (%) given on the printout may differ slightly from the values that would be obtained if manually calculated. The reason is that the measured and predicted values on the printout are rounded to two decimal places, the processor however, uses the actual values - measured to three decimal places - to calculate the % of predicted value. This can account for a possible variation. Where a difference exists, the values given on the printout are always the more accurate.*

Displaying the Results in Tabular Form

		PRED	BEST	MEAS1	MEAS2	MEAS3	%PRED
FVC	(l)	4.31		4.82			112
FEV 1.0	(l)	3.50		4.532			129
FEV 1/FVC	(%)	8.23		9.36			114
FEF .2-1.2	(l/s)						
FEF 25-75%	(l/s)						
FEF 75-85%	(l/s)						
PEF	(l/s)						
FEF 25%	(l/s)						
FEF 50%	(l/s)						
FEF 75%	(l/s)						
FMFT	(s)						
FVC	(l)						
FIV1	(l)						
FIV1/FVC	(%)						
FIV1/FVC	(%)						
PIF	(l/s)						
FIF50%	(l/s)						

Race Influences on Norm Values

According to the setting of the patients race the predicted values will differ. The differences are (according to ITS recommendations) as follows:

All languages except American:

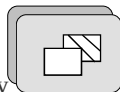
W/B	W (White):	values are calculated according to the given formulas (= 100%)
	B (Black):	85% of the given formulas

American Only:

C/H/B/A	C (Caucasian):	values are calculated according to the given formulas (= 100%)
	H (Hispanic):	values are calculated according to the given formulas (= 100%)
	B (Black):	85% of the given formulas
	A (Asian):	85% of the given formulas

The 85% race compensation is calculated only when the following normal values are selected: COMPOSITE; KNUDSON; CRAPO; MORRIS; POLGAR

Printout



Click the PRINT (copy) key to obtain a printout. The following is given. The graphs are printed as defined on the following page.

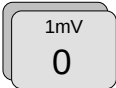
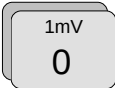
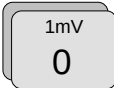
- The patient data.
- The selected norm values.
- The date of last calibration.
- The diagnostic statement (if enabled in Settings menu).
- The MTA identification.
- The user identification.
- The date and time of the printout.
- The software version.

Spiro Settings

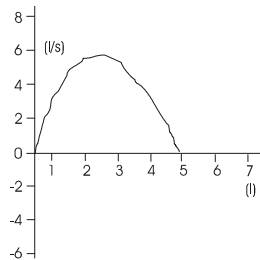
This menu option defines all the general settings. Settings made here are remembered when the unit is switched off. For normal use, the settings are made when the unit is first commissioned. However, the settings can be easily changed at any time for comparison purposes or individual preference. The settings menu is as follows:

Printout Graph Setup - Spirometry

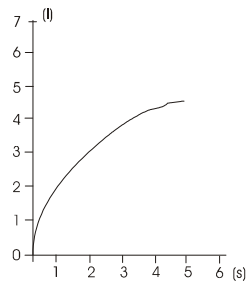
This defines the format and content of the printout when the PRINT key is pressed. The settings are as follows:

1st key	2nd key	3rd key	4th key	5th key	6 th key
					'0' Time Scale 10mm/s
					'1' Time Scale 20mm/s
					'2' Flow graph on (printed)
					'3' Flow graph off
					'4' Volume graph on (printed)
					'5' Volume graph off
					'6' Curve Format Best
					'7' Curve Format All

Spiro Settings



Flow Graph



Volume graph

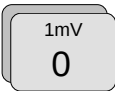
Printout Graph Setup - Miscellaneous

This defines the miscellaneous print settings as follows:

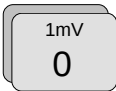
1s1st key



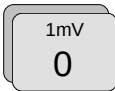
2nd key



3rd key



4th key



5th key



6 th key

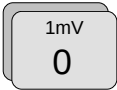
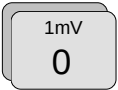
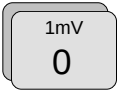
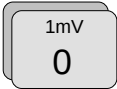
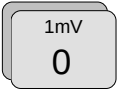
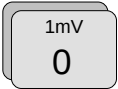
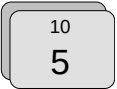
- '0' Diagnosis on (diagnosis printed)
- '1' Diagnosis off (diagnosis not printed)
- '2' PEF (l/m) - Peak Expiratory flow calculation litres/minute
- '3' PEF (l/s)- Peak Expiratory flow calculation litres/second

Spiro Settings

Normals

The Normal value standards are given at the end of this section- 'Diagnosis and Norm Value Tables'.

The effect of race on results is detailed previously.

1s1st key	2nd key	3rd key	4th key	5th key	6 th key
					'0' Knudson / ITS
					'1' Knudson 76/ ITS
					'2' Crapo / ITS
					'3' Morris / ITS
					'4' Polgar/ ITS
					'5' Composite / ITS
					'6' ECCS / Quanjer
					'7' Austria
					'8' Berlund / Quanjer
					'9' Finnish / Quanjer
					'0' Indian

**DIAGNOSIS ACCORDING TO 'ITS' RECOMMENDATIONS IS AVAILABLE WHEN AMERICAN IS SET -
SEE PAGE 20**

Spiro Settingss

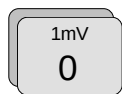
Measurement/ Report setup

The measurement setup defines how the FVC graph is displayed and printed. The report type defines the measurement on which the interpretation is to be based- Best or measurement 1.

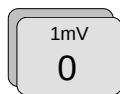
1s1st key



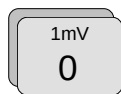
2nd key



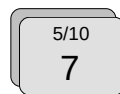
3rd key



4th key

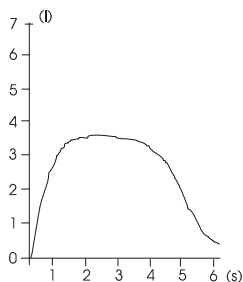


5th key

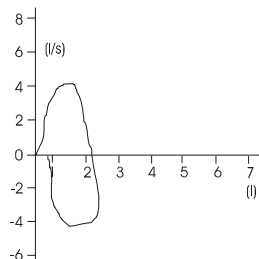


6 th key

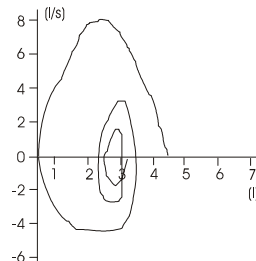
- '0' Measurement type Vol = f(t)
- '1' Measurement type Flow = f(Vol)
- '2' Flow- loop
- '4' Report Type: Best
- '5' Report Type: Measurement 1



Flow = f(t)



Flow = f(vol)



Flow = loop

Spiro Settings

American and Standard English

The unit language is set by the software. When English is installed it is possible to select American English or Standard English. The difference is as follows:

American

measurements in inches
temperature in degrees Fahrenheit
mains filter setting - 60Hz
date order mm-dd-yy

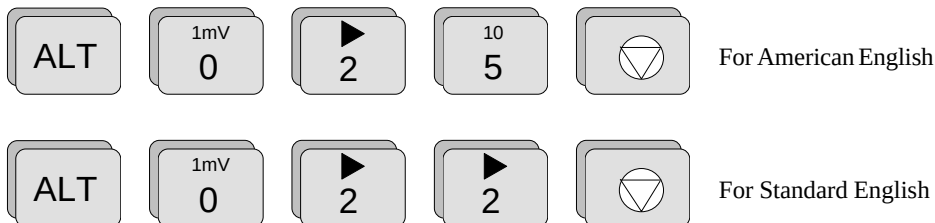
Standard English

measurements in centimetres
temperature in degrees centigrade.
mains filter setting - 50Hz
date order dd-mm-yy

Additionally, when American is set, further race settings are given and Spiro diagnosis is based on ITS recommendations - see later.

The default language is Standard English.

Define American or Standard English as follows:



Calibration

To calibrate, proceed as follows:

THE UNIT MUST BE CALIBRATED WITH THE FIRST PULMONARY FUNCTION TEST OF THE DAY, AFTER EVERY SIGNIFICANT TEMPERATURE CHANGE OR AFTER CHANGING THE SENSOR.

Select the Calibration menu option (ALT key then key '8').

The following screen is displayed:



Last calib.	:	25.03.99
BTPS Factor	:	1.090
Calib. Factor	:	1.002
Temperature	:	21 °C
Measured volume	:	0.00 l
Syringe Vol.	:	6.00 l

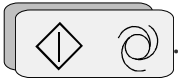
Calibration

Last Calibration	date of last calibration
BTPS	Factor calculated BTPS (=> Body Temperature, Ambient Pressure, Saturated with water vapour) value. This value compensates for the difference in inhaled and exhaled humidity. The unit is set for measuring exhaled volume (100% humidity, Temp 36.8°), and so when inhaled volume is measured this factor is applied. The SP-1 uses ambient temperature to calculate the BTPS factor. This is sufficient for accurate FIVC calculation. The formula used is as follows: $\text{BTPS} = 0.033 + \frac{273.15 + 36.8}{273.15 + T_u}$ Where: T_u is the ambient temperature in degrees centigrade 0.033 is the equivalent to 760mmHg at 22°C 273.15 is degrees absolute
Calibration Factor	calculated value between measured and effective calibration air volume
Temperature	ambient temperature in °C (or °F) dependent on device setting
Measured Volume	air volume measured by the system from the calibration pump
Reference Volume	entered air volume depending on the size of the calibration pump and times the air was pumped through the sensor; e.g. pumping 2 litres 3 times amounts to 6 litres (the recommended volume with a 2 litre pump is 4 litres and with a 3 litre pump 6 litres)

Calibration

Calibration Procedure

To calibrate the unit proceed as follows:

- **Connect the calibration pump to the sensor. Ensure that there are no air leaks.**
- **Press key '8' - the menu is displayed as shown on the previous page.**
- **Enter the ambient temperature.**
- **Enter the reference volume of air (depending on the size of the calibration pump and times of pumping; e.g. a 2 litre pump pumped 3 times = 6 litres).**
- **Wait 1 second.**
- **Click the start (auto) key** 
- **Pump 4 to 9 litres of air through the sensor (as set in reference volume).**
Note: Make sure that the flow sensor is kept still during the pumping operation.
While pumping, the unit records the volume being pumped through the flow sensor and indicates it on the display.
- **Press the STOP key when finished pumping** 
- **The message, `Calibration OK` appears on the display,**

If the message `EXCESSIVE DEVIATION!` or `CHANGE THE FILTER` appears on the screen after a calibration, it indicates that the difference between the measured volume and the entered volume is too great (>25%). Check the temperature setting, the syringe volume and the entered syringe volume. If these are all correct change the disposable mouthpiece and recalibrate.

Before recalibrating, the stored calibration values must be reset: to do this press the `ALT` and `I` keys.

Change the complete sensor assembly if calibration is still not possible and again press `ALT` and `I` before recalibrating.

Click the PRINT (copy) key to obtain a printout of the calibration report with measurement details, time and date of calibration, and a graph of the flow.



Explanation of Measured Values

FVC	Forced (expiratory) Vital Capacity. Volume achieved by the quickest possible exhalation after a maximal inhalation.
FEV _{0.5/1.0/3.0}	Forced expiratory volume. Lung volume in litres, measured after 0.5, 1.0 or 3 seconds forced expiration.
FEF	Forced Expiratory Flow Respiratory. Flow in terms of differing lung volumes measured in litres per second.
FEF _{25-75%}	flow speed of the expired air by 25 to 75% of the forced vital capacity (FVC).
FEF _{75-85%}	flow speed of the expired air by 75 to 85% of the forced vital capacity (FVC).
FEF _{25%}	flow speed of the expired air by 25% of the forced vital capacity (FVC).
FEF _{50%}	flow speed of the expired air by 50% of the forced vital capacity (FVC).
FEF _{75%}	flow speed of the expired air by 75% of the forced vital capacity (FVC).
FEF _{2-1.2}	averaged flow between 0.2 and 1.2 litres of the forced expired vital capacity.
PEF	Peak Expiratory Flow.
MEF	Maximal Expiratory Flow.
MEF _{75%}	flow speed of the expired air by 25% of the forced vital capacity (FVC).
MEF _{50%}	flow speed of the expired air by 50% of the forced vital capacity (FVC).
MEF _{25%}	flow speed of the expired air by 75% of the forced vital capacity (FVC).
	$MEF_{75\%} = FEF_{25\%}$ $MEF_{50\%} = FEF_{50\%}$ $MEF_{25\%} = FEF_{75\%}$

Explanation of Measured Values

ERV	Expiratory Reserve Volume. Possible further expiration starting from the normal expiration level.
IRV	Inspiratory Reserve Volume. Possible further inspiration starting from the normal inspiration level.
TV	Tidal Volume. Expirational and inspirational volumes during normal respiration.
SVC	Slow Vital Capacity. Lung volume measured from a complete expiration following a deep inspiration.
MV	Expired or Minute Ventilation. Volume of expired air in litres per minute measured over a minimum of one minute.
MVV	Maximum Voluntary Ventilation. Maximum volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible.
RR	Respiration Rate.
FMFT	Forced Mid-expiratory Flow Time. Time difference between the 25% and 75% points of the FVC.
FIVC	Forced Inspiratory Vital Capacity. Inspiration volume achieved between a maximal expiration and a maximal inspiration.
FIV_{1.0}	forced inspiratory air volume in litres measured in the first second.
FIV_{1.0} / FIVC	forced inspiratory air volume measured in the first second as a percentage of forced inspiratory vital capacity.
FIV_{1.0} / FVC	forced inspiratory air volume measured in the first second as a percentage of forced expiratory vital capacity.
PIF	Peak Inspiratory Flow. Maximum inspiratory flow speed in litres / second.
MIF	Maximum Inspiratory Flow. Maximum inspiratory flow in litres.
MIF_{50%}	flow speed by 50 % of the forced inspiratory vital capacity.

Diagnosis

The diagnostic interpretation is dependent upon the country. The factors used in the evaluation for diagnosis are automatically included in the respective language software and described in the following chapters.

Diagnosis Setting `International`

Note: When ,International, is set, diagnostic norms are predicted using the VC value (if taken). If VC values are not recorded, FVC is used. That is:

$\%VC = 100 * VC / VC \text{ predicted (when VC measurement taken), otherwise } 100 * FVC / FVC \text{ predicted}$

$FEV\% = 100 * FEV1 / VC \text{ (when VC measurement taken), otherwise } 100 * FEV1 / FVC$

Possible respiratory problems are diagnosed on evaluation of the following factors:

Diagnosis	%FVC (%SVC)	FEV1%
Normal Condition	>80%	>70%
Restrictive	<80%	-
Obstructive	-	<70%
Combined	<80%	<70%

The measurement FEV1/FVC or FEV1/VC will adapted on the screen and on the printout .

Diagnosis

Diagnosis Setting `American`

For the USA and Canada, diagnosis of possible respiratory problems is based on the ITS interpretation standard which uses the LLN (Lower Limits of Normal) calculations. These calculations apply to patients between the ages of 5 and 85. The LLN FEV1% value is calculated as follows:

	Male		Female	
Adult	>26 yrs:	Predicted FEV1% -9.2	>21 yrs:	Predicted FEV1% -11.1
Adolescent	19 to 25 yrs:	Predicted FEV1% x 0.848	19 to 20 yrs:	Predicted FEV1% x 0.805
Child	<18 yrs:	Predicted FEV1% x 0.826	<18 yrs:	Predicted FEV1% x 0.791

Using this LLN value, the diagnostic statements and their criteria are as follows:

Diagnosis	Criteria
Normal limits	FEV1/FVC% predicted is >80%
Borderline Obstruction	FEV1/FVC% is 80 to 100% of LLN
Mild Obstruction	FEV1/FVC% is 60 to 80% of LLN
Moderate Obstruction	FEV1/FVC% is 40 to 60% of LLN
Severe Obstruction	FEV1/FVC% is <40% of LLN
Mild Restriction	%FVCpredicted is 60 to 80%
Moderate Restriction	%FVCpredicted is 50 to 60%
Severe Restriction	%FVCpredicted is <50%

Norm Values

The norm values used for the calculation of predicted values are dependent upon the country.

- For Great Britain, Italy, Spain and Switzerland, the ECCS and Quanjer standards are used.
- For Sweden, the Swedish (Berglund) and Quanjer standards are used.
- In Finland the Finnish and Quanjer standards are used.
- In Austria the Austrian standards are used.
- In India the Indian norm values are used.
- In America and Canada the norm values that are used are Knudson, Knudson76, Crapo, Morris, Composite and Polgar. The American norm values are extended with values taken from the ITS (Intermountain Thoracic Society) recommendations.

The factors used in the evaluation for diagnosis and the specific norm values are included in the software and are described in the following pages.

IMPORTANT Due to great differences in the size of the lungs of children, there are no standard values for children under 6 years of age.

Norm Values

Norm Values for Countries Outside the USA

ECCS Values

The safety standards of the European Coal and Steel Community Standards (ECCS) are valid for adults of at least 25 years of age. Patients between the ages of 18 and 25 are calculated on the basis of a 25 year old. The calculation equations are as follows:

	Males	Females
SVC	$6.103 \times H - 0.028 \times A - 4.654$	$4.664 \times H - 0.024 \times A - 3.284$
FVC	$5.757 \times H - 0.026 \times A - 4.345$	$4.426 \times H - 0.026 \times A - 2.887$
FEV1	$4.301 \times H - 0.029 \times A - 2.492$	$3.953 \times H - 0.025 \times A - 2.604$
FEV1/SVC	$-0.179 \times A + 87.21$	$-0.192 \times A + 89.10$
MEF	$1.944 \times H - 0.043 \times A + 2.699$	$1.252 \times H - 0.034 \times A + 2.924$
PEF	$6.146 \times H - 0.043 \times A + 0.154$	$5.50 \times H - 0.030 \times A - 1.106$
MEF75	$5.459 \times H - 0.029 \times A - 0.470$	$3.218 \times H - 0.025 \times A + 1.596$
MEF50	$3.794 \times H - 0.031 \times A - 0.352$	$2.450 \times H - 0.025 \times A + 1.156$
MEF25	$2.605 \times H - 0.026 \times A - 1.336$	$1.050 \times H - 0.025 \times A + 1.107$

H: Height in meters

A: Age

Norm Values

Quanjer & Tammeling Comparisons

The Quanjer and Tammeling comparison is valid for children between the ages of 6 and 17 as follows:

	Boys	Girls
SVC = FVC	$1.00 \times H^{2.7}$	$0.95 \times H^{2.7}$
FEV1	$0.84 \times H^{2.7}$	$0.81 \times H^{2.7}$
FEV1/SVC	0.84	0.84
MEF = PEF	$8.2 \times H^{-6.8}$	$6.6 \times H^{-5.3}$
MEF50	$5.6 \times H^{-4.4}$	$4.6 \times H^{-3.3}$

H: Height in meters

Norm Values

Austrian Standard Values (Österreich)

Boys 5 - 17.99 years (1.09 - 1.96m)	Males 18 - 90 years (1.44 - 2.00m)
$\ln(\text{FVC}) = -1.142 + 1.259H + 0.004070A \sqrt{W}$	$\text{FVC} = -11.606 + 8.172H - 0.0339A \times H + 1.2869\ln(A)$
$\ln(\text{FEV1}) = -1.178 + 1.221H + 0.003841A \sqrt{W}$	$\text{FEV1} = -8.125 + 6.212H - 0.0300A \times H + 0.9770\ln(A)$
$\ln(\text{PEF}) = -0.214 + 0.921H + 0.0467A + 0.0020W$	$\sqrt{\text{PEF}} = 1.798 + 2.311\ln(H) + 0.0159A - 0.000248A^2$
$\ln(\text{PEF75}) = -0.077 + 0.770H + 0.0373A + 0.0025W$	$\sqrt{\text{PEF75}} = 1.581 + 1.854\ln(H) + 0.0213A - 0.000283A^2$
$\ln(\text{PEF50}) = -0.522 + 0.843H + 0.0300A + 0.0035W$	$\sqrt{\text{PEF50}} = 1.490 + 1.290\ln(H) + 0.0125A - 0.000218A^2$
$\ln(\text{PEF25}) = -1.576 + 1.166H + 0.0219A + 0.0021W$	$\sqrt{\text{PEF25}} = 1.314 + 0.898\ln(H) - 0.0083A - 0.000026A^2$
$\text{FEV1 \% CVF} = 101.99 - 1.191H^2 - 3.962\ln(A)$	$\text{FEV1 \% FVC} = 101.99 - 1.191H^2 - 3.962\ln(A)$
Girls 5 - 17.99 years (1.10 - 1.82m)	Females 16 - 90 years (1.40 - 1.90m)
$\ln(\text{FVC}) = -3.842 + 4.1632 \sqrt{H} + 0.1341\sqrt{A} - 1.614\text{Fi}$	$\text{FVC} = -10.815 + 6.640H - 0.0408A \times H + 1.7293\ln(A)$
$\ln(\text{FEV1}) = -3.877 + 3.9809 \sqrt{H} + 0.1485\sqrt{A} - 1.322\text{Fi}$	$\text{FVC1} = -6.995 + 5.174H - 0.0314A \times H + 1.0251\ln(A)$
$\ln(\text{PEF}) = 0.411 + 1.793\ln(H) + 0.4251\ln(A) - 0.910\text{Fi}$	$\sqrt{\text{PEF}} = 1.832 + 1.838\ln(H) + 0.0078A - 0.0001722 A^2$
$\ln(\text{MEF75}) = 0.455 + 1.616\ln(H) + 0.3738\ln(A) - 0.861\text{Fi}$	$\sqrt{\text{PEF75}} = 1.779 + 1.421\ln(H) + 0.0096A - 0.000179A^2$
$\ln(\text{MEF50}) = 0.256 + 1.643\ln(H) + 0.3481\ln(A) - 1.089\text{Fi}$	$\sqrt{\text{PEF50}} = 1.561 + 1.177\ln(H) + 0.0045A - 0.000140A^2$
$\ln(\text{MEF25}) = -0.772 + 2.002\ln(H) + 0.3063\ln(A) - 0.409\text{Fi}$	$\sqrt{\text{PEF25}} = 1.372 + 0.938\ln(H) - 0.0152A - 0.000036A^2$
$\text{FEV1 \% FVC} = 92.33$	$\text{FEV1 \% FVC} = 118.993 - 3.0320H^2 - 6.9053\ln(A)$

H = Height in meters A = Age in years

W = Weight in kg Fi = Body fat index = $H/\sqrt[3]{W}$

Norm Values

Swedish Standards (Berglund)

The Swedish (Berglund) standard is valid for adults between the ages of 18 and 75 years as follows:

	Hommes	Femmes
FEV%	$91.79 - (0.373 \times A)$	$92.11 - (0.261 \times A)$
FVC=SVC	$1.09 [(4.81 \times H) - (0.020 \times A) - 2.81]$	$1.09 [(4.04 \times H) - (0.022 \times A) - 2.35]$
FEV	$1.01.09 [(3.44 \times H) - (0.033 \times A) - 1.00]$	$1.09 [(2.67 \times H) - (0.027 \times A) - 0.54]$

A: Age

H: Height in meters

Norm Values

Finnish Standards

The Finnish standard is valid for adults from the age of 18 years as follows:

Males	
SVC (l)	$\exp [(-0.00833 \times A) + (0.6309 \times \log A) + (-1.4750 / H) + 0.9047]$
FEV1 (l)	$\exp [(-0.00587 \times A) + (0.2756 \times \log A) + (-1.1655 / H) + 1.0980]$
FVC (l)	$\exp [(-0.00827 \times A) + (0.5860 \times \log A) + (-1.4468 / H) + 0.9461]$
FEV1 / SVC (%)	$\exp [(0.00246 \times A) + (-0.3553 \times \log A) + (0.3095 / H) + 2.1933]$
FEV1 / FVC (%)	$\exp [(0.00240 \times A) + (-0.3104 \times \log A) + (0.2813 / H) + 2.1519]$
PEF (l/s)	$\exp [(-0.00211 \times A) + (0.1049 \times \log A) + (-0.6774 / H) + 1.3255]$
Females	
SVC (l)	$\exp [(-0.01016 \times A) + (0.6995 \times \log A) + (-1.4518 / H) + 0.7763]$
FEV1 (l)	$\exp [(-0.00920 \times A) + (0.4772 \times \log A) + (-1.3284 / H) + 0.9296]$
FVC (l)	$\exp [(-0.00982 \times A) + (0.6358 \times \log A) + (-1.4137 / H) + 0.8320]$
FEV1 / SVC (%)	$\exp [(0.00096 \times A) + (-0.2223 \times \log A) + (0.1233 / H) + 2.1533]$
FEV1 / FVC (%)	$\exp [(0.00062 \times A) + (-0.1586 \times \log A) + (0.0853 / H) + 2.0975]$
PEF (l/s)	$\exp [(-0.00677 \times A) + (0.4017 \times \log A) + (-0.7422 / H) + 0.9661]$

A: Age

H: Height in meters

log: Logarithm to base 10

Norm Values

Indian Equations

The Indian equations are valid for patients from the age of 7 years as follows:

	Males	Females
	<30 years old:	
FVC	$0.055 \times H + 0.019 \times A - 6.058$	$0.030 \times H + 0.006 \times A - 2.284$
FEV1	$0.039 \times H - 0.010 \times A - 3.266$	$0.025 \times H - 0.011 \times A - 1.424$
	>30 years old:	
FVC	$0.054 \times H - 0.018 \times A - 4.832$	$0.043 \times H - 0.010 \times A - 3.755$
FEV1	$0.037 \times H - 0.022 \times A - 2.650$	$0.032 \times H - 0.012 \times A - 2.580$
FEV1/FVC	$-0.1756 \times H - 0.2457 \times A - 119.346$	$-0.0334 \times H - 0.2146 \times A - 94.8867$
SVC	$0.0522 \times H - 0.0114 \times A - 4.859$	$0.0587 \times H - 0.0296 \times A - 5.927$
FEV3	$0.0485 \times H - 0.0183 \times A - 4.138$	$0.0533 \times H - 0.0105 \times A - 5.660$
FEF25-75%	$0.0173 \times H - 0.0407 \times A - 1.6108$	$0.0245 \times H - 0.0336 \times A - 0.1399$
PEF	$0.0850 \times H - 0.0187 \times A - 6.2083$	$0.0497 \times H - 0.0018 \times A - 2.7154$
FEF50	$0.0195 \times H - 0.0365 \times A - 1.7383$	$0.0272 \times H - 0.0279 \times A - 0.2704$
FEF75	$0.0088 \times H - 0.0301 \times A - 1.0402$	$0.0113 \times H - 0.0288 \times A - 0.5012$
MVV	$1.3056 \times H - 0.5228 \times A - 93.2102$	$0.7149 \times H - 0.3624 \times A - 25.0208$

A: Age, H: Height in meters

Norm Values for USA and Canada

Morris Norm Values

The Morris equations are valid for women between 56 and 72 inches tall and within the age range of 20 to 90 years, and for men between 58 and 80 inches tall and within the age range of 20 to 90 years as follows:

	Males	Females
FVC	$0.1480 \times H - 0.0250 \times A - 4.241$	$0.1150 \times H - 0.0240 \times A - 2.852$
FEV1	$0.0920 \times H - 0.0320 \times A - 1.260$	$0.0890 \times H - 0.0250 \times A - 1.932$
FEV1/FVC	$-0.3118 \times H - 0.2422 \times A + 107.120$	$-0.0679 \times H - 0.1815 \times A + 88.700$
FEF.2 - 1.2	$0.1090 \times H - 0.0470 \times A + 2.010$	$0.1450 \times H - 0.0360 \times A - 2.532$
FEF25 - 75	$0.0470 \times H - 0.0450 \times A + 2.513$	$0.0600 \times H - 0.0300 \times A + 0.551$
FEF75 - 85	$0.0130 \times H - 0.0230 \times A + 1.210$	$0.0250 \times H - 0.0210 \times A + 0.321$

The Morris normals are extended with the following:

	Males	Females
FEV0.5	$0.0831 \times H - 0.0152 \times A - 1.914$	$0.0605 \times H - 0.0185 \times A - 0.809$
FEV3	$-0.1359 \times H - 0.0271 \times A - 3.512$	$-0.1123 \times H - 0.0257 \times A - 2.745$
FEV3/FVC	$-0.1593 \times H - 0.1450 \times A + 112.090$	$-0.2380 \times H - 0.1630 \times A + 118.160$
MVV	$3.4040 \times H - 1.2600 \times A - 21.400$	$2.0500 \times H - 0.5700 \times A - 5.500$

Norm Values for USA and Canada

Crapo Norm Values

The Crapo equations are valid for men between 61 and 77 inches tall and within the age range of 18 to 89 years, and for women between 57 and 71 inches tall and within the age range of 18 to 89 years as follows:

	Males	Females
FVC	$0.1524 \times H - 0.0214 \times A - 4.650$	$0.1247 \times H - 0.0216 \times A - 3.590$
FEV1	$0.1052 \times H - 0.0244 \times A - 2.190$	$0.0869 \times H - 0.0255 \times A - 1.578$
FEV3	$0.1359 \times H - 0.0271 \times A - 3.512$	$0.1123 \times H - 0.0257 \times A - 2.745$
FEV1/FVC	$-0.3302 \times H - 0.1520 \times A + 110.490$	$-0.5131 \times H - 0.2520 \times A + 126.580$
FEF25 - 75	$0.0518 \times H - 0.0380 \times A + 2.133$	$0.0391 \times H - 0.0460 \times A + 2.683$
MVV	$3.4040 \times H - 1.2600 \times A - 21.400$	$2.0500 \times H - 0.5700 \times A - 5.500$

The Crapo normals are extended with the following ITS equations:

	Males	Females
FEV0.5	$0.0831 \times H - 0.0152 \times A - 1.914$	$0.0605 \times H - 0.0185 \times A - 0.809$
FEV3/FVC	$-0.1593 \times H - 0.1450 \times A + 112.090$	$-0.2380 \times H - 0.1630 \times A + 118.160$

A: Age

H: Height in inches

Norm Values for USA and Canada

Morris and Crapo Norm Values for Children

The following equations are valid for children within the age range of 7 to 18 years:

BOYS 7 - 17.99 years (1.09 - 1.96m) White			GIRLS 7 - 17.99 years (1.09 - 1.96m) White		
FVC(ml) =	$3.58 \times 10^{-4} \times H^{3.18}$	SD = 13%	FVC(ml) =	$2.57 \times 10^{-3} \times H^{2.78}$	SD = 14%
FVC _{1.0} (ml) =	$7.74 \times 10^{-4} \times H^{3.0}$	SD = 13%	FVC _{1.0} (ml) =	$3.79 \times 10^{-3} \times H^{2.68}$	SD = 14%
PEFR(l/min) =	$3.35 \times 10^{-4} \times H^{2.79}$	SD = 18%	PEFR(l/min) =	$2.58 \times 10^{-3} \times H^{2.37}$	SD = 18%
FEF _{75-75%} (l/min) =	$3.98 \times 10^{-4} \times H^{2.46}$	SD = 26%	FEF _{75-75%} (l/min) =	$3.79 \times 10^{-3} \times H^{2.16}$	SD = 28%
BOYS 7 - 17.99 years (1.09 - 1.96m) Black/Asian			GIRLS 7 - 17.99 years (1.09 - 1.96m) Black/Asian		
FVC(ml) =	$1.07 \times 10^{-3} \times H^{2.93}$	SD = 17%	FVC(ml) =	$8.34 \times 10^{-4} \times H^{2.98}$	SD = 15%
FVC _{1.0} (ml) =	$1.03 \times 10^{-3} \times H^{2.92}$	SD = 17%	FVC _{1.0} (ml) =	$1.14 \times 10^{-3} \times H^{2.89}$	SD = 15%
PEFR(l/min) =	$1.74 \times 10^{-4} \times H^{2.92}$	SD = 22%	PEF(l/min) =	$5.51 \times 10^{-4} \times H^{2.68}$	SD = 20%
FEF _{75-75%} (l/min) =	$3.61 \times 10^{-4} \times H^{2.60}$	SD = 36%	FEF _{75-75%} (l/min) =	$1.45 \times 10^{-3} \times H^{2.34}$	SD = 30%
BOYS 7 - 17.99 years (1.09 - 1.96m) Mexican American			GIRLS 7 - 17.99 years (1.09 - 1.96m) Mexican American		
FVC(ml) =	$1.06 \times 10^{-3} \times H^{2.97}$	SD = 13%	FVC(ml) =	$1.25 \times 10^{-3} \times H^{2.92}$	SD = 14%
FVC _{1.0} (ml) =	$1.73 \times 10^{-3} \times H^{2.85}$	SD = 13%	FVC _{1.0} (ml) =	$1.61 \times 10^{-3} \times H^{2.85}$	SD = 14%
PEFR(l/min) =	$7.69 \times 10^{-4} \times H^{2.63}$	SD = 17%	PEF(l/min) =	$6.97 \times 10^{-4} \times H^{2.64}$	SD = 18%
FEF _{75-75%} (l/min) =	$9.13 \times 10^{-4} \times H^{2.45}$	SD = 25%	FEF _{75-75%} (l/min) =	$1.20 \times 10^{-3} \times H^{2.40}$	SD = 24%

Norm Values for USA and Canada

Knudson Norm Values

The Knudson equations are valid for both children and adults in specific groups according to age and height as shown following:

	Males	Females
	H = 44 to 61 inches, A = 6 to 11 yrs	H = 42 to 58 inches, A = 6 to 10 yrs
FVC	$0.1039 \times H + 0.0 \times A - 3.376$	$0.1092 \times H + 0.0 \times A - 3.749$
FVC0.5	$0.0760 \times H + 0.0430 \times A - 3.050$	$0.0480 \times H + 0.0610 \times A - 1.740$
FEV1	$0.0884 \times H + 0.0 \times A - 2.814$	$0.0853 \times H + 0.0 \times A - 2.758$
FEV1/FVC	$-0.2065 \times H + 0.0 \times A + 100.439$	$-0.4849 \times H + 0.6655 \times A + 109.974$
FEF25 - 75	$0.0859 \times H + 0.0 \times A - 2.320$	$0.0559 \times H + 0.0 \times A - 0.812$
PEF	$0.1980 \times H + 0.1660 \times A - 8.061$	$0.1240 \times H + 0.1570 \times A - 3.920$
FEF50	$0.0960 \times H + 0.0 \times A - 2.545$	$0.0 \times H + 0.1846 \times A + 0.736$
FEF75	$0.0434 \times H + 0.0 \times A - 1.015$	$0.0277 \times H + 0.0 \times A - 0.166$
MVV	$3.0300 \times H - 0.8160 \times A - 37.900$	$2.7600 \times H + 3.4000 \times A - 108.120$
	H = 55 to 76 inches A = 12 to 25 yrs	H = 52 to 72 inches, A = 11 to 20 yrs
FVC	$0.1499 \times H + 0.0739 \times A - 6.887$	$0.1057 \times H + 0.0699 \times A - 4.447$
FVC0.5	$0.0760 \times H + 0.0430 \times A - 3.050$	$0.0480 \times H + 0.0610 \times A - 1.740$
FEV1	$0.1318 \times H + 0.0636 \times A - 6.118$	$0.0892 \times H + 0.0694 \times A - 3.762$
FEV1/FVC	$-0.2065 \times H + 0.0 \times A + 100.439$	$-0.4849 \times H + 0.6655 \times A + 109.974$
FEF25 - 75	$0.1369 \times H + 0.0749 \times A - 6.199$	$0.0709 \times H + 0.1275 \times A - 2.801$
PEF	$0.1980 \times H + 0.1660 \times A - 8.061$	$0.1240 \times H + 0.1570 \times A - 3.920$
FEF50	$0.1379 \times H + 0.1150 \times A - 6.385$	$0.0732 \times H + 0.1111 \times A - 2.304$
FEF75	$0.1008 \times H - 0.0057 \times A - 4.242$	
MVV	$4.6800 \times H + 1.8000 \times A - 192.320$	$2.7600 \times H + 3.4000 \times A - 108.12$
<i>For patients over 18 yrs, the following ITS equations apply:</i>		
FEV3	$0.1359 \times H - 0.0271 \times A - 3.512$	$0.1123 \times H - 0.0257 \times A - 2.745$
FEV3/FVC	$-0.1593 \times H - 0.1450 \times A + 112.090$	$-0.2380 \times H - 0.1630 \times A + 118.160$
	H = 62 to 77 inches, A = 26 to 120 yrs	H = 58 to 71 inches, A = 21 to 120 yrs
FVC	$0.1524 \times H - 0.0214 \times A - 4.650$	$0.1247 \times H - 0.0216 \times A - 3.590$
FVC0.5	$0.0831 \times H - 0.0152 \times A - 1.914$	$0.0605 \times H - 0.0185 \times A - 0.809$
FEV1	$0.1052 \times H - 0.0244 \times A - 2.190$	$0.0869 \times H - 0.0255 \times A - 1.578$
FEV3	$0.1359 \times H - 0.0271 \times A - 3.512$	$0.1067 \times H - 0.0257 \times A - 2.745$
FEV1/FVC	$0.0 \times H - 0.1050 \times A + 86.686$	$-0.4704 \times H - 0.1896 \times A + 121.678$
FEF.2 - 1.2	$0.1090 \times H - 0.0470 \times A + 2.010$	$0.1450 \times H - 0.0360 \times A - 2.532$
FEF25 - 75	$0.1471 \times H - 0.0363 \times A - 4.518$	$0.0531 \times H - 0.0344 \times A + 1.128$
FEF75 - 85	$0.0130 \times H - 0.0230 \times A + 1.210$	$0.0250 \times H - 0.0210 \times A + 0.321$
PEF	$0.2390 \times H - 0.0350 \times A - 5.990$	$0.1240 \times H - 0.0250 \times A - 0.740$
FEF25	$0.0900 \times H - 0.0200 \times A + 2.726$	$0.0690 \times H - 0.0190 \times A + 2.147$
FEF50	$0.1737 \times H - 0.0366 \times A - 5.409$	$0.0681 \times H - 0.0289 \times A + 0.609$
FEF75	$0.0787 \times H - 0.0230 \times A - 2.483$	$0.0244 \times H - 0.0259 \times A + 1.118$
MVV	$3.0300 \times H - 0.8160 \times A - 37.900$	$2.1400 \times H - 0.6850 \times A - 4.870$
<i>In addition, there are the following ITS equations:</i>		
FEV3/FVC	$-0.1593 \times H - 0.1450 \times A + 112.090$	$-0.2380 \times H - 0.1630 \times A + 118.160$

Norm Values

Knudson 76 Norm Values

The Knudson 76 equations are valid for both males and females in specific age groups as follows:

A: Age

H: Height in inches

	Males	Females
	Age <25 yrs	Age <20 yrs
FVC	$0.1270 \times H + 0.078 \times A - 5.508$	$0.0838 \times H + 0.092 \times A - 3.469$
FVC0.5	$0.0762 \times H + 0.043 \times A - 3.054$	$0.0483 \times H + 0.061 \times A - 1.738$
FEV1	$0.1168 \times H + 0.045 \times A - 4.808$	$0.0686 \times H + 0.085 \times A - 2.703$
FEV3	$0.1321 \times H + 0.066 \times A - 5.531$	$0.0838 \times H + 0.086 \times A - 3.417$
FEV1/FVC	$-0.2210 \times H - 0.140 \times A + 103.64$	$-0.2819 \times H - 0.109 \times A + 107.38$
FEF25 - 75	$0.1499 \times H + 0.0 \times A - 5.443$	$0.0635 \times H + 0.121 \times A - 0.893$
PEF	$0.1981 \times H + 0.166 \times A - 8.060$	$0.1245 \times H + 0.157 \times A - 3.916$
FEF25	$0.1778 \times H + 0.147 \times A - 7.054$	$0.1118 \times H + 0.144 \times A + 3.365$
FEF50	$0.1295 \times H + 0.081 \times A - 4.975$	$0.0864 \times H + 0.120 \times A + 2.531$
FEF75	$0.0813 \times H + 0.0 \times A - 2.455$	$0.0 \times H + 0.139 \times A - 0.692$
	Age ≥25 yrs	Age ≥20 yrs
FVC	$0.1651 \times H - 0.029 \times A - 5.459$	$0.0940 \times H - 0.022 \times A - 1.774$
FVC0.5	$0.0940 \times H - 0.017 \times A - 2.746$	$0.0483 \times H - 0.014 \times A - 0.406$
FEV1	$0.1321 \times H - 0.027 \times A - 4.203$	$0.0686 \times H - 0.021 \times A - 0.794$
FEV3	$0.1600 \times H - 0.031 \times A - 5.245$	$0.0889 \times H - 0.023 \times A - 1.633$
FEV1/FVC	$-0.2210 \times H - 0.140 \times A + 103.64$	$-0.2819 \times H - 0.109 \times A + 107.38$
FEF25 - 75	$0.1143 \times H - 0.031 \times A - 1.864$	$0.0533 \times H - 0.024 \times A - 1.171$
PEF	$0.2388 \times H - 0.035 \times A - 5.993$	$0.1245 \times H - 0.025 \times A - 0.735$
FEF25	$0.2235 \times H - 0.035 \times A - 5.618$	$0.1092 \times H - 0.025 \times A + 0.132$
FEF50	$0.1753 \times H - 0.015 \times A - 5.400$	$0.0889 \times H - 0.013 \times A - 0.444$
FEF75	$0.1118 \times H - 0.012 \times A - 4.143$	$0.0 \times H - 0.014 \times A - 3.042$

Norm Values

Composite Norm Values

Selection of the Composite normals provides selected equations taken from other tables as follows:

Value	Equation Reference
FVC	Knudson
FEV1	Knudson
FEV3	Crapo
FEF25 - 75	Knudson
FEF75 - 85	Morris
FEF.2 - 1.2	Morris
MVV	Crapo
SVC	Knudson (same as FVC)

Norm Values

Polgar Norm Values

The Polgar equations are valid for both children and adults in specific groups according to age as follows:

A: Age
H: Height in inches.

The remaining values are taken from the ITS equations.

	Males	Females
	Age under 18 years	Age under 18 years
FVC	$H^3 \cdot 0.0000071 + H^2 \cdot 0.00057 - H \cdot 0.0123 + 0.14$	$H^3 \cdot 0.0000076 + H^2 \cdot 0.00048 + H \cdot 0.0112 + 0.13$
FVC0.5	$H \cdot 0.076 + A \cdot 0.043 - 3.05$	-
FEV1	$H^3 \cdot 0.0000087 + H \cdot 0.00035 - H \cdot 0.0086 + 0.1$	$H^3 \cdot 0.0000086 + H^2 \cdot 0.00035 - H \cdot 0.0086 + 0.1$
FEF25 - 75%	$H \cdot 0.1109 - 3.46$	$H \cdot 0.1109 - 3.46$
PEF	$H \cdot 0.2219 - 7.09$	$H \cdot 0.2219 - 7.09$
MVV	$H \cdot 4.68 - A \cdot 1.8 - 192.32$	$H \cdot 2.76 - A \cdot 3.4 - 108.12$
	Age 18 to 25 years	Age 18 to 20 years
FVC	$H \cdot 0.1499 + A \cdot 0.0739 - 6.887$	$H \cdot 0.1057 + A \cdot 0.0699 - 4.447$
FVC0.5	$H \cdot 0.0760 + A \cdot 0.0430 - 3.050$	$H \cdot 0.0480 + A \cdot 0.00610 - 1.740$
FEV1	$H \cdot 0.1318 + A \cdot 0.0636 - 6.118$	$H \cdot 0.0892 + A \cdot 0.0694 - 3.762$
FEF25 - 75	$H \cdot 0.1369 + A \cdot 0.0749 - 6.199$	$H \cdot 0.0709 + A \cdot 0.1275 - 2.801$
PEF	$H \cdot 0.1980 + A \cdot 0.1660 - 8.061$	$H \cdot 0.1240 + A \cdot 0.1570 - 3.920$
FEF50	$H \cdot 0.1379 + A \cdot 0.1150 - 6.385$	$H \cdot 0.0732 + A \cdot 0.1111 - 2.304$
FEF75	$H \cdot 0.1008 - A \cdot 0.0057 - 4.242$	$H \cdot 0.0617 + A \cdot 0.2923 - 4.401$
MVV	$H \cdot 4.68 + A \cdot 1.8 - 192.32$	$H \cdot 2.76 + A \cdot 3.4 - 108.12$
	Age over 26 years	Age over 20 years
FEF3	-	$H \cdot 0.1067 - A \cdot 0.0257 - 2.745$
FEF2-1.2	$H \cdot 0.1090 - A \cdot 0.0470 + 2.010$	$H \cdot 0.1450 - A \cdot 0.0360 - 2.532$
FEF25 - 75%	$H \cdot 0.1471 - A \cdot 0.0363 - 4.518$	$H \cdot 0.0531 - A \cdot 0.0344 + 1.128$
FEF75 - 85%	$H \cdot 0.0130 - A \cdot 0.0230 + 1.210$	$H \cdot 0.0250 - A \cdot 0.0210 + 0.321$
PEF	$H \cdot 0.2390 - A \cdot 0.0350 - 5.990$	$H \cdot 0.1240 - A \cdot 0.0250 - 0.740$
FEF25	$H \cdot 0.0900 - A \cdot 0.0220 + 2.726$	$H \cdot 0.0690 - A \cdot 0.0190 + 2.147$
FEF50	$H \cdot 0.1737 - A \cdot 0.0366 - 5.409$	$H \cdot 0.0681 - A \cdot 0.0289 + 0.609$
FEF75	$H \cdot 0.0787 - A \cdot 0.0230 - 2.483$	$H \cdot 0.0244 - A \cdot 0.0259 + 1.118$
MVV	$H \cdot 3.03 - A \cdot 0.816 - 37.9$	$H \cdot 2.14 - A \cdot 0.685 - 4.87$

Changing the Flow Sensor SP-250 (RS-232)



Changing the Flow Sensor SP-250 (RS-232)

WARNING

THE DISPOSABLE MOUTHPIECE IS DESIGNED FOR ONE-TIME USE TO ELIMINATE THE DANGER OF CROSS CONTAMINATION - DO NOT USE THE MOUTHPIECE FOR MORE THAN ONE PATIENT.

1. Remove disposable mouthpiece (1) by gently but firmly pulling it away from the handle (2).
2. Discard the complete assembly.
3. Position new disposable mouthpiece (Part No. 2.100077) and gently but firmly click it in position.

NOTE: The disposable mouthpiece can only be positioned in one direction and no force is necessary to insert it on the handle. Ensure that the orientation is correct by checking the guide protrusion in sensor against the guide slot in the handle.

4. Calibrate the sensor and unit as detailed on page 23.

Care & Maintenance

Self-test

Initiate a self-test of the unit as follows by pressing keys ALT > 0 > 3 > 3. A table giving information for the service staff is displayed. To obtain a printout press `P` when the table is displayed. Exit this screen by pressing the ENTER key.

12 Monthly Check

The unit should undergo a technical safety check every 12 months. This safety check should include the following:

- Visual inspection of the unit, the sensor and cables.
- Electrical safety tests according to IEC 601-1.
- Calibration of the sensor as detailed on page 23.

The test results must be documented.

Lifed Items

There are no lifed items in the AT-2plus

Care & Maintenance

WARNINGS: ONLY THE SENSOR HANDLE AND CABLE CAN BE CLEANED - DO NOT ATTEMPT TO CLEAN THE DISPOSIBLE MOUTHPIECE.

DISCONNECT THE SENSOR FROM THE UNIT BEFORE CLEANING. DO NOT, UNDER ANY CIRCUMSTANCES, IMMERSE THE APPARATUS INTO A CLEANING LIQUID OR STERILIZE WITH HOT WATER, STEAM, OR AIR.

Cleaning the Sensor Assembly

The sensor casing can be cleaned with a soft damp cloth on the surface only. Where necessary a domestic non-caustic cleaner can be used for grease and finger marks.

Cleaning the Sensor Cable

ALIGN THE SENSOR CABLE IN SUCH A WAY AS TO PREVENT ANYONE STUMBLING OVER IT OR ANY DAMAGE CAUSED BY THE WHEELS OF INSTRUMENT TROLLEYS.

The sensor cable should not be exposed to excessive mechanical stress. Whenever disconnecting the cable, hold the plug and not the cable. Store the cable in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.

The cable can be wiped with soapy water. Sterilization, if required, should be done with gas only and not with steam. To disinfect, wipe the cable with hospital standard disinfectant.

Cleaning the Thermal Print Head

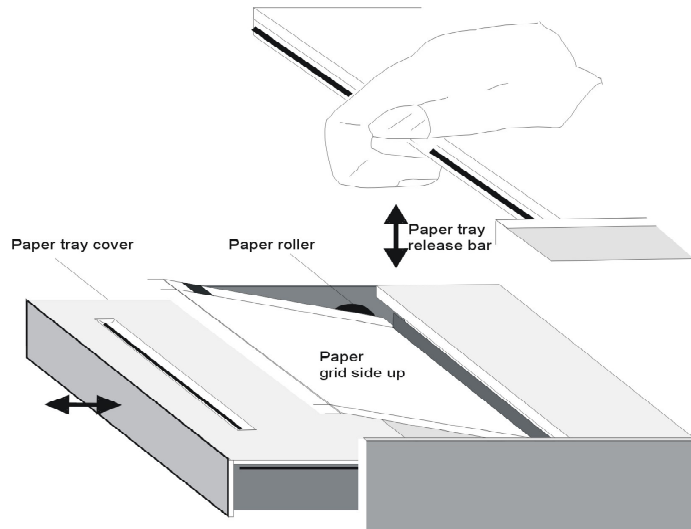
If the printer is used a lot, a residue of printers ink (from the grid on the paper) can build up on the print head. This can cause the print quality to deteriorate. We recommend therefore that every month the print head is cleansed with alcohol as follows:

Remove the paper tray. The thermal printhead is found under the paper tray release catch.

With a tissue dampened in alcohol, gently rub the printhead to remove the ink residue. If the printhead is badly soiled, the colour of the paper grid ink (i.e. red or green) will show on the tissue.

Replacing the Recording Paper

The recording paper must be replaced as soon as the end of the paper is indicated by a red stripe on the lower edge. After the indication first appears, there are about 8 pages left. However, we recommend that the paper be replaced immediately. If no paper is left, the printing process is interrupted and a warning is given on the screen. To replace the paper proceed as follows:



Replacing the Recording Paper

- **Place fingers under the retaining bar and pull directly upwards. The paper tray cover releases.**
- **Withdraw the cover from the unit. DO NOT FORCE, THE PAPER TRAY COVER RUNS FREELY OVER THE DEDICATED RUNNERS.**
- **Remove any remaining paper from the paper tray.**
- **Place a new paper pack into the paper tray with the printed (grid) side facing upwards.**
- **Place the beginning of the paper over the black paper roller on the paper tray cover.**
- **Return the paper tray cover in position and press firmly until secure.**
- **Press the STOP key to transport the paper to the start position.**

SCHILLER can only guarantee perfect printouts when SCHILLER original chart paper or chart paper of the same quality is used.

Thermal Paper Handling

The thermal paper used in the At-2plus requires slightly different handling to normal paper as it can react with chemicals and to heat. However, when the following points are remembered, the paper will give reliable results:

The following points apply to both storage, and when archiving the results.

1. Before use, keep the paper in its original cardboard cover. Do not remove the cardboard cover until the paper is to be used.
2. Store in a cool, dark and dry area.
3. Do not store near chemicals e.g. sterilisation liquids.
4. In particular do not store in a plastic cover.
5. Certain glues can react with the paper - do not attach the printout onto a mounting sheet with glue.

Technical Data

Technical data subject to change without notice.

Safety standard:	BF according to IEC and complying with the following:
	RL 93/42/EEC
	EN 60601-1:1990
	IEC 601-1
	pr EN 1441:1994
	IEC 513:1994
Protection class:	I according to IEC, VDE, SEV
	IIa according to RL 93/42/EEC
Method of Measurement:	Pneumotachometer
Measurement Ranges:	Flow: 0 to ±14 l/s; Volume: 0 to ±11 litres
Measurement Accuracy:	±2%
Flow Impedance:	Less than 0.2 mbar * s/l at 12 l/s
Measured Values:	FVC, ERV, IRV, TV, FVC, FEV _{0.5} , FEV _{1.0} , FEV _{3.0} , FEV _{0.5} /SVC, FEV _{1.0} /FVC, FEV _{3.0} /VC, FEF _{0.2-1.2} (litres), FEF _{25-75%} , FEF _{75-85%} , PEF, MEF _{75%} , MEF _{50%} , MEF _{25%} , MV, MVV, FIVC, FIV _{1.0} , FIV _{1.0} /FIVC, FIV _{1.0} /FVC, PIF, MIF _{50%} .
	Comparison pre/post medication possible.
	Extrapolated predicted values
Prediction Equation:	Adults: ECCS / Austria / Berglund / Finnish / Indian / Morris / Crapo / Knudson / Knudson 76 / Polgar / Composite
	Children: Quanjer & Tammeling / Austria / Indian / Knudson / Knudson 76 / Polgar
Standards Compliance:	ATS, OSHA, NIOSH

Accessories & Ordering

The SCHILLER representatives in your country will keep all spirometry parts and accessories. In case of a problem or if you require the address of your local representative, contact the SCHILLER-headquarters in Switzerland. The staff there will be happy to process your order and to supply you with information regarding all SCHILLER products. When ordering, please specify that the required item is for the AT-2PLUS SPIROand advise the following details:

- Article Description
- Article Number
- Your Name
- Address
- Phone Number

Accessories	Part No.
Calibration pump 2 litres	2. 100 027
Pneumotacho sensor SP-250	2. 200 TBA
Pack of 10 disposable sensors for SP-150 / 250	2. 100 077
Nose Clip	2. 100 084

Spirometry Tips - How To Do It and Common Pitfalls and Problems

How to Do It

To ensure an acceptable result, the FVC manoeuvre must be performed with maximum effort immediately following a maximum inspiration; it should have a rapid start and the spirogram should be a smooth continuous curve.

To achieve good results, carefully explain the procedure to the patient, ensuring that he/she is sitting erect with feet firmly on the floor (the most comfortable position, though standing gives a similar result in adults, and in children the vital capacity is greater in the standing position). Apply a nose clip to the patient's nose (this is recommended but not essential) and urge the patient to:

- breathe in fully;
- seal his/her lips around the mouthpiece;
- blast air out ,as fast and as far as you can‘ until the lungs are completely empty;
- breathe in again as forcibly and fully as possible.

If only peak expiratory flow is being measured then the patient need only exhale for a couple of seconds. Essentials are:

- a good seal on the mouthpiece and
- very vigorous effort right from the start of the manoeuvre and continuing until absolutely no more air can be exhaled;
- no leaning forward during the test.

Spirometry Tips - How To Do It and Common Pitfalls and Problems

Remember, particularly in patients with airflow obstruction, that it may take many seconds to fully exhale. It is also important to recognise those patients whose efforts are reduced by chest pain or abdominal problems, or by fear of incontinence, or even just by lack of confidence. There is no substitute for careful explanation and demonstration - demonstrating the manoeuvre to the patient will overcome 90% of problems encountered and is critical in achieving satisfactory results. Observation and encouragement of the patient's performance are also crucial. Be sure to examine the spirogram for acceptability and reproducibility, and to correct the measurements to BTPS (see Calibration).

Attention to fine detail in the performance of the breathing manoeuvre is critical to obtaining reliable results.

At least three technically acceptable manoeuvres should be obtained, ideally with less than 0.2 L variability for FEV1 (and FVC) between the highest and second highest result. Quote the largest value. The American Thoracic Society (ATS) provides the following guidelines for manoeuvre performance.

FVC

- Minimum of 3 acceptable blows
- A rapid start is essential: this is defined as a back-extrapolated volume of <5% of FVC or 0.15 L, whichever is greater.
- At least 6 second expiration
- End of test - no change in volume for at least 1 second after exhalation time of 6 seconds; or FET >15 seconds; or stopped for clinical reasons
- Spirometer temperature between 17 and 40 degrees Celsius; measure spirometer temperature to one degree Celsius
- Use of nose clip is encouraged
- Sitting or standing
- Reproducibility: the highest and second highest FVC should agree to within 0.2L

Spirometry Tips - How To Do It and Common Pitfalls and Problems

FEV1

- As for FVC
- Take largest FEV1 even if not from the same curve as the best FVC
- „Zero time“ determined by back-extrapolation - extrapolated volume should be <5% of FVC or 0.15 litres, whichever is greatest
- Smooth, rapid take off with no: hesitation, cough, leak, tongue obstruction, glottic closure, valsava or early termination
- Reproducibility: the highest and second highest FEV1 should agree to within 0.2L

Spirometry Tips - How To Do It and Common Pitfalls and Problems

Patient-Related Problems

The most common patient-related problems when performing the FVC manoeuvre are:

- Submaximal effort
- Leaks between the lips and mouthpiece
- Incomplete inspiration or expiration (prior to or during the forced manoeuvre)
- Hesitation at the start of the expiration
- Cough (particularly within the first second of expiration)
- Glottic closure
- Obstruction of the mouthpiece by the tongue
- Vocalisation during the forced manoeuvre
- Poor posture.

Once again, demonstration of the procedure will prevent many of these problems, remembering that all effort-dependent measurements will be variable in patients who are uncooperative or trying to produce low values.

Glottic closure should be suspected if flow ceases abruptly during the test rather than being a continuous smooth curve. Recordings in which cough, particularly if this occurs within the first second, or hesitation at the start has occurred should be rejected. Vocalisation during the test will reduce flows and must be discouraged - performing the manoeuvre with the neck extended often helps.

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